Interview Summary	Application No.	Applicant(s)	
	09/758,993	GREENWALD ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Jeffrey E. Russel*.

(2) *Michael N. Mercanti*.

(3) *Peggy Albanese*.

(4) _____.

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Date of Interview: *25 February 2003* .

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____ .

Claim(s) discussed: *All* .

Identification of prior art discussed: *All* .

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Jeffrey E. Russel

Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

_____
Examiner's signature, if required

Summary of Record of Interview Requireme

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Fax draft amendment avoids obviousness-type double patenting rejection and rejection over the Greenwald et al article. Discussed amending claim 1 to insert functional definition of Z-[D]y from page 8, line 31, of the specification to distinguish over the Zier et al article. Also discussed the use of proviso limitations to distinguish over the Zier et al article. Examiner recommended that at least one of the dependent claims not rejected over the Zier et al article be re-written in independent form .

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---------FAX COVER LETTER---------

FROM: Michael N. Mercanti

DATE: 2/24/03

RE: USSN 09/758,993

PLEASE DELIVER THE FOLLOWING PAGES TO:

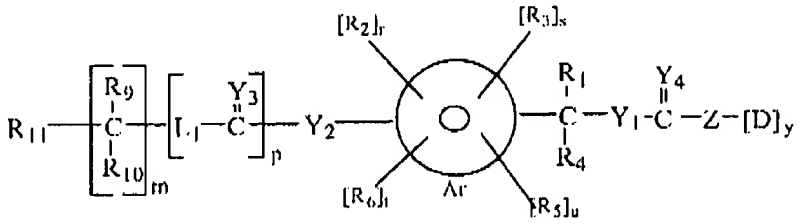
TO:	Ex. J. E. Russel
FAX NO:	703 746 5175
MESSAGE:	Proposed Amendments for discussion

----------transmitting 8 pages, including cover sheet----------

If there are any problems with reception of this fax, please call or fax sender to advise. Thank you.

PROPOSAL FOR INTERVIEW

1. (Amended) A compound of Formula I:

(I) 

wherein:

L_1 is a bifunctional linking moiety;

D is a moiety that is a leaving group, or a residue of a compound to be delivered into a cell;

Z is covalently linked to $[D]_y$, wherein Z is selected from the group consisting of: a moiety that is actively transported into a target cell, a hydrophobic moiety, and combinations thereof;

Y_1, Y_2, Y_3 and Y_4 are each independently O, S, or NR_{12};

R_{11} is a mono- or divalent polymer residue;

R_1, R_4, R_9, R_{10} and R_{12} are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{3-12} branched alkyls, C_{3-8} cycloalkyls, C_{1-6} substituted alkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, C_{1-6} heteroalkyls, and substituted C_{1-6} heteroalkyls;

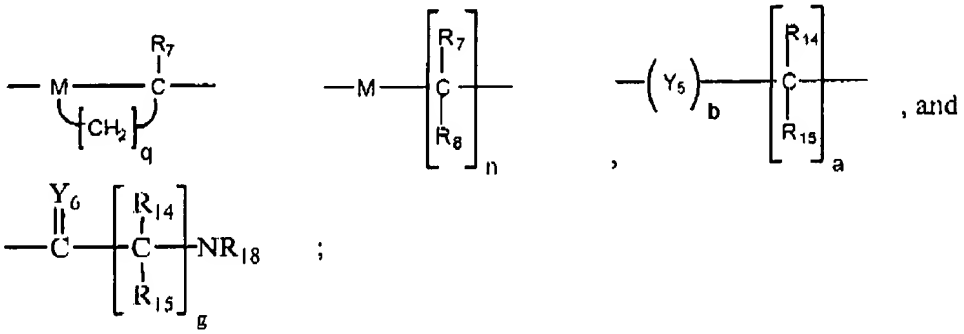
R_2, R_3, R_5 and R_6 are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{1-6} alkoxy, phenoxy, C_{1-8} heteroalkyls, C_{1-8} heteroalkoxy, substituted C_{1-6} alkyls, C_{3-8} cycloalkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, halo-, nitro-, [and] cyano-, carboxy-[,] C_{1-6} carboxyalkyls and C_{1-6} alkylcarbonyls;

Ar is a moiety which when included in Formula (I) forms a multi-substituted aromatic hydrocarbon or a multi-substituted heterocyclic group;

(m), (r), (s), (t), and (u) are independently zero or one;

(p) is zero or a positive integer; and (y) is 1 or 2.

2. (Amended) The compound of claim 1, wherein L_1 is selected from the group consisting of:



wherein:

M is X or Q; where X is an electron withdrawing group;

Q is a moiety containing a free electron pair positioned three to six atoms from $-\overset{\overset{Y_3}{\|}}{C}-$;

(a) and (n) are independently zero or a positive integer;

(b) is zero or one;

(g) is a positive integer;

(q) is three or four;

R_7, R_8, R_{14}, R_{15} and R_{18} are independently selected from the group which defines R_9; and

Y_5 and Y_6 are independently O, S, or NR_{12}.

6. (Amended) The compound of claim 4 wherein the peptide ranges in size from [about] 2 to about 10 amino acid residues.

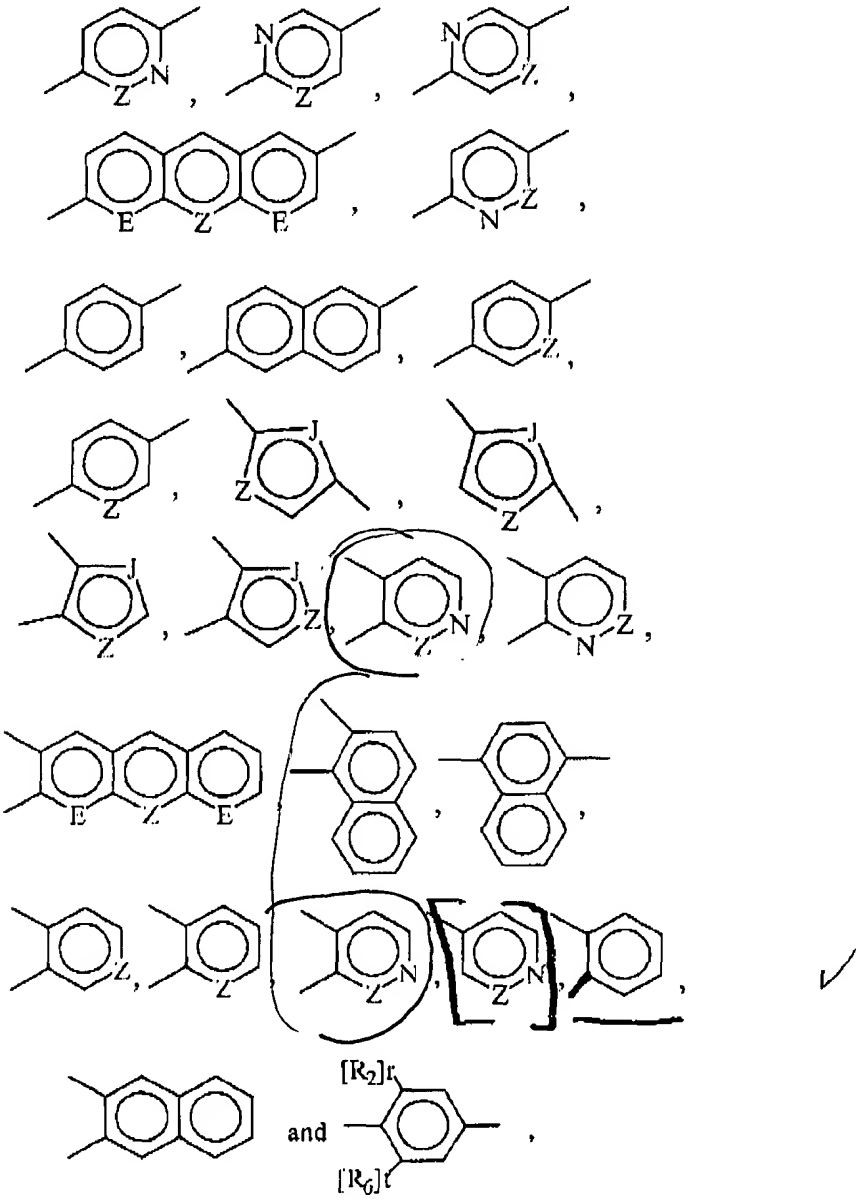
7. (Amended) The compound of claim 6 wherein the peptide is Gly-Phe-Leu-Gly (SEQ ID NO:1) or Gly-Phe-Leu.

8. (Amended) The compound of claim 1 wherein each D moiety is independently a residue of an active biological material [, or H].

9. (Amended) The compound of claim 1 wherein each D moiety is independently a residue of an anticancer agent, an anticancer prodrug, a detectable tag, [and] or combinations thereof.

12. (Amended) The compound of claim 1 wherein at least one D moiety is a leaving group selected from the group consisting of [as] N-hydroxybenzotriazolyl, halogen, N-hydroxy-phthal-imidyl, p-nitrophenoxy, imidazolyl, N-hydroxysuccinimidyl, thiazolidinyl thione, and combinations thereof.

13. (Amended) The compound of claim 1 wherein Ar is selected from the group consisting of,



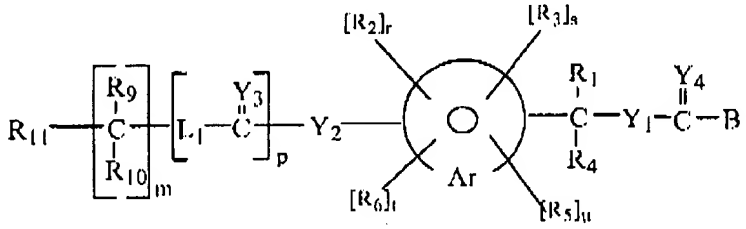
wherein J is selected from the group consisting of O, S, and N-R_{19}, E and Z are independently C-R_{19} or N-R_{19} and R_{19} is selected from the group consisting of hydrogen, C_{1-6} alkyl, C_{3-12} branched alkyl, C_{3-8} cycloalkyl, C_{1-6} substituted alkyl, C_{3-8} substituted

cycloalkyl, aryls, substituted aryl, aralkyl, C_{1-6} heteroalkyl, and substituted C_{1-6} heteroalkyls.

17. (Amended) The compound of claim 2, wherein X is selected from the group consisting of

Y_6 R_{17}
‖ |
O, NR_{12}, -C-N-, S, SO and SO_2 where R_{17} is independently selected from the group consisting of hydrogen, C_{1-6} alkyl, C_{3-12} branched alkyl, C_{3-8} cycloalkyl, C_{1-6} substituted alkyl, C_{3-8} substituted cycloalkyl, aryl, substituted aryl, aralkyl, C_{1-6} heteroalkyl, and substituted C_{1-6} heteroalkyl. **MAKE PLURALS ?** If you want.

31. (Amended) A method of preparing a tetrapartate prodrug comprising reacting a compound of formula:

III 

with a compound of formula:

IV Lx Z $[D]_y$; ← bond signs

wherein B is a leaving group for Formula III;

L_1 is a bifunctional linking moiety;

D is a moiety that is a leaving group, or a residue of a compound to be delivered into a cell;

Lx is a leaving group for Formula IV;

Z is covalently linked to $[D]_y$, wherein Z is selected from the group consisting of: a moiety that is actively transported into a target cell, a hydrophobic moiety, and combinations thereof;

R_1, R_4, R_9, R_{10} and R_{12} are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{3-12} branched alkyls, C_{3-8} cycloalkyls, C_{1-6} substituted alkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, C_{1-6} heteroalkyls, and substituted C_{1-6} heteroalkyls;

R_2, R_3, R_5 and R_6 are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{1-6} alkoxy, phenoxy, C_{1-8} heteroalkyls, C_{1-8} heteroalkoxy, substituted C_{1-6} alkyls, C_{3-8} cycloalkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, halo-, nitro-, [and] cyano-, carboxy-, C_{1-6} [carboxyalkyl] carboxyalkyls and C_{1-6} [alkylcarbonyl] alkylcarbonyls;

Ar is a moiety which when included in Formula (III) forms a multi-substituted aromatic hydrocarbon or a multi-substituted heterocyclic group;

(m), (r), (s), (t), and (u) are independently zero or one;

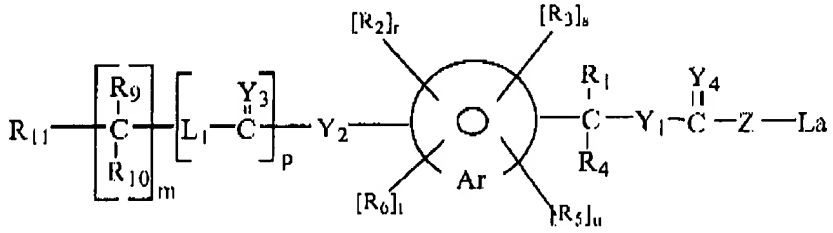
(p) is zero or a positive integer;

(y) is one or two; [and]

Y_1, Y_2, Y_3 and Y_4 are each independently O, S, or NR_{12} ; and

R_{11} is a monovalent or divalent polymer residue.

32. (Amended) A method of preparing a tetrapartate prodrug comprising reacting a compound of formula

V 

with at least one biologically active material; wherein

L_1 is a bifunctional linking moiety;

La is a leaving group for Formula V;

Z is covalently linked to [at least one biologically active material,] La and wherein Z is selected from the group consisting of: a moiety that is actively transported into a target cell, a hydrophobic moiety, and combinations thereof;

R_1, R_4, R_9, R_{10} and R_{12} are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{3-12} branched alkyls, C_{3-8} cycloalkyls, C_{1-6} substituted alkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, C_{1-6} heteroalkyls, and substituted C_{1-6} heteroalkyls;

R_2, R_3, R_5 and R_6 are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{1-6} alkoxy, phenoxy, C_{1-8} heteroalkyls, C_{1-8} heteroalkoxy, substituted C_{1-6} alkyls, C_{3-8} cycloalkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, halo-, nitro-, [and] cyano-, carboxy-, C_{1-6} [carboxyalkyl] carboxylalkyls and C_{1-6} [alkylcarbonyl] alkylcarbonyls;

Ar is a moiety which when included in Formula (V) forms a multi-substituted aromatic hydrocarbon or a multi-substituted heterocyclic group;

(m), (r), (s), (t), and (u) are independently zero or one;

(p) is zero or a positive integer;

Y_1, Y_2, Y_3 and Y_4 are independently O, S, or NR_{12} ; and

R_{11} is a monovalent or divalent polymer residue;

whereby, Z is covalently linked to the at least one biologically active material after the reaction.

33. (Amended) A method of treating a disease or disorder in an animal, that comprises administering a pharmaceutically acceptable composition comprising an effective amount of a compound of claim 1,where D is a moiety that is a [leaving group, or] [a]residue of a compound to be delivered into a cell; to an animal in need thereof.